IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ALISHA AUSTIN, INDIVIDUALLY AND AS PARENT ON BEHALF OF S.A., A MINOR , Plaintiffs v. ABBOTT LABORATORIES, and ABBOTT LABORATORIES, INC., Defendants.	CASE NO.: JUDGE: COMPLAINT AND JURY DEMAND

COMPLAINT

Plaintiff Alisha Austin, individually and as mother of Plaintiff S.A., a minor, ("Plaintiff"), pursuant to Fed. R. Civ. P. 17(c)(1)(A), hereby brings this Complaint against Defendants Abbott Laboratories and Abbott Laboratories, Inc., (collectively "Abbott" or "Defendants") and states and alleges as follows:

NATURE OF THE ACTION

This is an action to redress the injuries suffered by Plaintiff Alisha Austin and her minor daughter, Plaintiff S.A., who has spent the majority of her life fighting against the harm caused by bovine-milk based (or "cow-based") infant formula manufactured, marketed, and sold by Defendant Abbott Laboratories Inc. ("Abbott"). Necrotizing enterocolitis (NEC) is a potentially fatal disease that largely affects low birth-weight babies who are fed cow-based formula. Plaintiff S.A., a prematurely born, low birth-weight baby, was fed Defendant's cow-based Similac products and developed NEC as a result.

Plaintiffs bring claims against Defendants arising from Defendants' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, labeling, of its cow-based formula.

PARTIES

1. At all times material hereto, Plaintiff Alisha Austin ("Plaintiff Austin") was and is an adult domiciled in, and a citizen of, the State of Ohio. Plaintiff Austin currently resides in Toledo, Lucas County, Ohio. Ms. Austin is the mother and guardian of S.A. (Plaintiff "S.A."), a minor.

2. Plaintiff S.A. is a minor child domiciled in, and a citizen of, the State of Ohio. In accordance with Loc. R. 8.1, as Plaintiff S.A. is a minor child, only her initials are being used. Plaintiff S.A. currently resides in Toledo, Lucas County, Ohio with her mother, Plaintiff Austin. Plaintiff S.A. was born prematurely on 6/26/2020 at St. Vincent Medical Center in Toledo, Ohio.

3. Defendant Abbott Laboratories was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Illinois with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen, and domiciliary of Illinois.

4. Defendant Abbott Laboratories, Inc. was at all times material hereto and is now a corporation duly organized, incorporated, and existing under the laws of the State of Delaware with its principal place of business and headquarters in the State of Illinois and is thus a resident, citizen and domiciliary of Delaware and Illinois. Defendant Abbott Laboratories, Inc. is a wholly owned subsidiary of its parent company Abbott Laboratories.

5. On information and belief, for all purposes relevant to this Complaint, Abbott

Laboratories and Abbott Laboratories, Inc. functioned as one entity; thus, this Complaint will refer to them collectively as "Abbott" and/or "Defendants."

6. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including Ohio, premature infant formula including Similac Human Milk Fortifier, Similac Special Care, Similac NeoSure, and Liquid Protein Fortifier. At all material times hereto, Abbott solely or jointly designed, developed, formulated, prepared, manufactured, provided instructions for, packaged, labeled, promoted, marketed, distributed and/or sold Similac products specifically targeting medical providers and parents of preterm infants, including but not limited to Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifier, and "Similac Special Care Formulas" such as Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30.

7. Defendant Abbott advertises that it provides the "#1 Formula Brand, Backed by Science" and claims to have "over 90 years of innovations" in infant formula.

JURISDICTION AND VENUE

8. This is an action for damages which exceed the sum of $75,000.00, exclusive of costs, interest, and attorneys' fees.

9. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and the Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

10. This Court has personal jurisdiction over Defendants pursuant to Ohio Revised Code 2307.382 because Defendants are authorized to conduct business and do conduct business

in the State of Ohio, purposefully direct and/or directed their actions toward and/or within Ohio and consented to being sued in Ohio by registering an agent for service of process in Ohio. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within the State of Ohio, the damages were sustained by Plaintiff within the State of Ohio, and the damages sustained by Plaintiff were a result of Defendants' actions and/or inactions, described herein, that were purposefully directed at and/or within the State of Ohio. Further, Defendants have marketed, promoted, distributed, and/or sold their products described herein in the State of Ohio. Defendants have sufficient minimum contacts with this state and/or sufficiently avail themselves of the markets in the state through their promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

11. Venue of this action is proper in this Court pursuant to 28 U.S.C. §1391(b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district.

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

12. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of pregnancy are completed, like Plaintiff S.A. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

13. Nutrition for preterm babies, like Plaintiff S.A., is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

14. Historically, there are three types of nutrition for preterm babies: parenteral nutrition for feed intolerance such as a feeding tube, human milk whether it is the mother's own milk or donor milk, and cow's milk-based formulas and fortifiers. Cow's milk-based products ("Cow's Milk Products") were believed to be good for the growth of premature, low birth weight babies. While the Cow's Milk Products were good for bulking up these babies quickly, science and research have advanced in recent years confirming strong links between cow-based products and Necrotizing Enterocolitis ("NEC") causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-bovine based products. Despite knowledge of a causal connection between Cow's Milk Products and NEC, the manufacturers of the Cow's Milk Products, including Defendants, did nothing to change their product, packaging, guidelines, instructions, and/or warnings and continue to promote and sell the Cow's Milk Product versions.

15. NEC is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut.

16. With normal absorption in the small intestine, the cells lining the lumen of the intestines have microvilli that magnify the surface area available for uptake. Nutrients are absorbed by these cells, then transported through the cells, and released where they are then transported to the rest of the body through the bloodstream and lymphatic system. The cells keep out the bacteria and toxins that are present in the intestines which would be harmful if absorbed into the other tissues of the body. The tight junctions between each cell play a major role in preventing the bacteria and toxins from entering the body.

17. If these tight junctions are broken down, harmful bacteria and toxins are able to enter the baby's bloodstream and lymphatics, which induces an inflammatory response in the baby's intestinal walls. These toxins further breakdown and weaken the tight, intercellular junctions, and as a result, bacteria, toxins, and plasma escape into the surrounding interstitial spaces resulting in a condition known as "third-spacing" and sepsis. This process all begins with the administration of Cow's Milk Products and can lead to sepsis, multi-system organ failure, and death.

18. The classic signs and symptoms of NEC experienced by vulnerable preterm babies after ingesting the Cow's Milk Products include, but are not limited to: irritability, crying, pain, abdominal distention, hyperthermia, tachycardia, decreased bowel sounds, lethargy, reduced urine output, shock, free air in the abdomen, elevated white blood count, tenderness, portal venous gas, greenish discoloration, worsening or persistent thrombocytopenia, completely gasless abdomen, repeated feeding intolerance, intestinal strictures, passage of meconium through patent processus vaginalitis, and fixed and dilated loop on serial abdominal radiographs.

19. As early as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was six to ten times more common in exclusively formula-fed babies than in those fed breast milk alone and three times more common than in those who received formula plus breast milk. Babies born at more than 30 weeks gestation confirmed that NEC was rare in those whose diet included breast milk, but it was 20 times more common in those fed formula only. A. Lucas,

T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990).

20. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon

General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011). This same report stated that premature infants who are not breast-fed are 138% more likely to develop NEC. *Id.*

21. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk…. If the mother's own milk is unavailable...pasteurized donor milk should be used." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e84l (2012).

22. A study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards, as well as length, weight, and head circumference gain. The authors concluded that "this study provides data showing that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet." A. Hair, *et al.*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk Products, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula companies such as Defendants.

23. Another study published in 2013 reported the first randomized trial in extremely

premature infants of exclusive human milk versus preterm bovine-based formula. The study found a significantly higher rate of surgical NEC in infants receiving the bovine preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU (Newborn Intensive Care Unit). E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013).

24. In a study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with significant morbidity and mortality. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July).

25. The same study found that NEC "is the most frequent and lethal gastrointestinal disorder affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death." *Id.* The study noted: "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease." *Id.* The study further found that advances in formula development have made it possible to prevent necrotizing enterocolitis, and the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

26. In another study published in 2014, it was reported that an exclusive human milk

diet, devoid of Cow's Milk Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al*., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

27. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an exclusive human milk diet is associated with "significant benefits" for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were no feeding-related adverse outcomes." Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet,* BREASTFEEDING MEDICINE, 11-2 (2016).

28. In 2017, a publication by the American Society for Nutrition noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of bovine milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an exclusive human milk diet resulted in a much lower incidence of NEC. While the study noted that bovine milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the bovine-based products significantly increase the risk of NEC and death. Jocelyn Shulhan, *et al.*, *Current Knowledge*

of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products, ASN ADV. NUTR., 8(1):80-91 (2017).

29. The FDA requires manufacturers of prescription medications to study their medications and perform drug trials and collect data to determine the safety and efficacy of their drugs and to determine the likelihood of side effects and to continuously study the drug's use to review adverse outcomes and create proper warnings and instructions; however, because baby products, such as Defendants' Cow's Milk Products, are not drugs,[1] Defendants have not performed such trials and have not collected data on when and how the products should be fed. Despite knowing for decades that their Cow's Milk Products are associated with and are significantly increasing NEC and death in premature infants, and are far more dangerous than most prescription drugs, Defendants have done nothing to stop or lessen NEC or death.

30. If Defendants had performed the pharmacovigilance required by drug manufacturers for their premature infant formulas and fortifiers, which a reasonably prudent manufacturer would have done, Defendants' Cow's Milk Products would not have been fed to S.A., she would not have developed NEC, and she would not have suffered the devastating effects of NEC.

31. There are human milk-based formulas and fortifier products which are safer feasible alternatives to Defendants' Cow's Milk Products.

The Marketing

32. Notwithstanding strong and overwhelming medical evidence establishing the extreme dangers that Cow's Milk Products pose for preterm infants, Defendants have marketed

[1] Defendants' Cow's Milk Products do not require a prescription from a healthcare provider; rather, they are readily available to the average consumer.

their Cow's Milk Products as an equally safe alternative to breast milk and have promoted these products as necessary for additional nutrition and growth. Defendants have specifically marketed their formulas and fortifiers as necessary to the growth and development of preterm infants, when instead, these products pose a known and substantial risk to these babies.

33. Defendants have also engaged in tactics reminiscent of tobacco manufacturers by trying to "hook" moms when they are most vulnerable. They often offer free formula and other freebies and coupons in "gift baskets" given to mothers in hospitals, medical clinics, and even left at residential charities where out-of-town families have to stay when their babies are being treated for a substantial amount of time in the neonatal intensive care units of hospitals. By doing this, Defendants are able to create brand loyalty under the guise of a "medical blessing" so that these vulnerable parents continue to use formula to feed their babies after they leave the hospital, resulting in great expense to parents, significant risk to the babies, and substantial profit to Defendants.

34. Defendants are also able to hook a customer base for other products they manufacture as the customer base ages. For example, Abbott's Similac website advertises its products Ensure and Zone Perfect as "healthy living" and markets its "therapeutics," such as Glucerna, Alliance, Mi Glucerna, and Nepro, which are products largely marketed to aging and geriatric populations.

35. Defendants' self-serving and nefarious tactics go back decades, as these companies continue to fight for their respective market share by scaring mothers with newborn infants, especially those who are higher risk because they are born preterm. Defendants falsely advertise that their products are healthier or even necessary for adequate nutrition and that formula is the only appropriate choice for modern mothers. In fact, these tactics are purposefully

designed to encourage parents to buy into the myth that formula is best, which further discourages mothers from breastfeeding at all and which further reduces the supply of available breast milk and ensures that more of their formula will be purchased.

36. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting with the following statement, "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000).

37. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly (WHA) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "There should be no advertising or other form of promotion to the general public [of breast milk substitutes]." In Article 5.2, the Code states that "manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…." *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

38. While Defendants have publicly acknowledged the Code since its adoption and

claim to support the effort to educate mothers to breastfeed, they insidiously undermine breastfeeding efforts and flout the Code. See "Don't Push It: Why the Formula Milk Industry Must Clean up its Act," SAVE THE CHILDREN, 2018. In the decades since adoption of the Code, Defendants continue to aggressively market and exploit the vulnerabilities of these families by advertising directly to the new parents' darkest fears – that by not buying and using these products, they will somehow hurt their newborns by not giving them the very best chance of survival. In fact, in the WHO's 2018 Status Report on this issue, it was noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to US $44.8 billion and "is expected to rise to US $70.6 billion by 2019." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report* 2018. Geneva: World Health Org., 2018, p. 21.

39. These companies continue to aggressively market because it works, especially since they consistently employ unfair and deceptive tactics from the inception of the Cow's Milk Products. For example, the name "Similac," as in, it is "similar to lactation," is deceptively designed to perpetuate a false sense that its product is similar to human breast milk.

40. Moreover, an advertisement for Similac on the back cover of the April 2004 issue of American Baby Magazine makes repeated references and comparisons to breast milk for brain and visual development, along with greater calcium absorption and greater bone density. *See* Angela B. Hyderkhan, *Mammary Malfunction: A Comparison of Breastfeeding and Bottlefeeding Product Ads with Magazine Article Content,* (2005) LSU MASTER'S THESES,

667, https://digitalcommons.lsu.edu/gradschool_theses/667/.

41. In addition to perpetuating the myth that these Cow's Milk Products are similar to breast milk, Defendants have also intentionally deceived the public into believing that healthcare providers believe these products are superior to breast milk or even ideal and that physicians and institutions endorse the Cow's Milk Products.

42. A marketing report commissioned by Abbott in March 1998 summarized consumer reactions to several informational advertising pamphlets on Similac. Abbott found that the advertisements that scored highest in terms of whether consumers would actually buy the product included the claims about being the "1st Choice of Doctors." Defendant Abbott found that using doctor recommendations and the supposed "science" behind the formula further drove consumer interest and purchases.

43. Another study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. R.S. Parker, *Ethical Considerations in the Use of Direct-to-Consumer Advertising and Pharmaceutical Promotions: The Impact on Pharmaceutical Sales and Physicians,* J. OF BUS. ETHICS, 48, 279-290 (2003). Thus, by a company marketing in advance to the public that a product is recommended by physicians, the public buys more of the product, and then the physicians are actually more likely to recommend the product in the future, further perpetuating and fueling a deceptive cycle.

44. Manufacturers have also repeatedly used their relationships with hospitals and the discharge process to encourage mothers to substitute Cow's Milk Products for human breastmilk even after they leave the hospital. K.D. Rosenberg, C.A. Eastham*, et al, Marketing Infant Formula Through Hospitals: The Impact of Commercial Hospital Discharge Packs on*

Breastfeeding, AM J PUBLIC HEALTH, 98(2):290-295 (2008).

45. Indeed, most hospitals in the U.S. distribute "commercial discharge bags packaged as smart diaper bags containing various coupons, advertisements, baby products, and infant formula samples." Yeon Bai, *et al*, *Alternative Hospital Gift Bags and Breastfeeding Exclusivity*, ISRN NUTR., article ID 560810: 2 (2013). Providing commercial gift bags to breastfeeding mothers sends confusing signals and has been shown to negatively impact breastfeeding rates. *Id.* at 5. However, the practice continues since it is a very effective way to exploit potential formula customers.

46. With the proliferation of the internet, Defendants have updated their tactics to advertise heavily on the internet and through their websites. For example, Defendant Abbott uses its website to boast that their line of Similac products provides "complete nutrition for immune support and brain and eye development."

47. Defendant Abbott also offers new mothers "Similac Rewards for a Strong Start" on their website, advertising up to "$400 in great offers," and even though the fine print says that "offers may vary," they advertise providing "formula coupons and samples," "nutrition guidance," and a "free Shutterfly photo book."

48. One study estimates that formula manufacturers spent $4.48 billion on marketing and promotion in 2014 alone. P. Baker, et al., *Global Trends and Patterns of Commercial Milk-based Formula Sales: Is an Unprecedented Infant and Young Child Feeding Transition Underway?,* PUBLIC HEALTH NUTRITION (2016).

49. The contradictory messages mothers receive from images, articles, and advertising in doctors' offices, hospitals, popular magazines, websites, and now social media campaigns are often most successful when employing medical authorities to suggest that

breastfeeding is unnecessary and difficult, if not impossible, to achieve. *See generally* B.L. Hausman, *Rational Management: Medical Authority and Ideological Conflict in Ruth Lawrence's Breastfeeding: A Guide for the Medical Profession,* TECH. COMM. QUARTERLY, 9(3), 271-289 (2000).

50. Another study found that exposure to infant feeding information through media advertising has a negative effect on breastfeeding initiation. A. Merewood, *et al, Exposure to Infant Feeding Information in the Media During Pregnancy is Associated with Feeding Decisions Postpartum*, Am. Public Health Ass'n 138th Ann. Meeting (2010).

51. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that breastfeeding rates decreased after the frequency of infant formula advertisements increased. J. Stang, *et al*, *Health Statements Made in Infant Formula Advertisements in Pregnancy and Early Parenting Magazines: A Content Analysis*, INFANT CHILD ADOLESC NUTR., 2(1):16-25 (2010). In addition, the authors found that infant formula company websites, along with their printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into believing that they are purchasing a product equivalent or superior to human milk, which further induces reliance on information from a biased source. *Id.*

52. Defendants have become adept at developing psychological advertising campaigns which attempt to create a perception of "mommy wars." One advertisement from Defendant Abbott, which received significant attention and won advertising awards to combat the threat to formula sales by rising breastfeeding rates, was called "The Mother 'Hood." [2] In

[2] (https://www.youtube.com/watch?list=RDJUbGHeZCxe4&v=JUbGHeZCxe4&feature=emb%20rel%20end.)

this ad, Abbott depicts a gang war between mostly mothers and a few fathers arguing about the best way to take care of their babies. The ad is effective in so much as it is manipulative. The advertisement at one point depicts three "bottle feeding moms," and one of them proclaims: "Oh look, the breast police have arrived." The ad then depicts the "breastfeeding moms" with arrogant and superior appearing faces, and even disdainful mannerisms, with one of the moms proclaiming in a condescending voice, "100% breast fed – straight from the source," and a second mom grasping her breast in a profane manner. The negative portrayal of breastfeeding moms is subtle, but powerful, and casts the breastfeeding moms as judgmental and nasty, while portraying the bottle-feeding moms as nurturing victims. At the end, they all come together to rescue a baby in an errant stroller rolling down a hill, and the ad says, "Welcome to the sisterhood of motherhood" before closing with their product name and new hashtag and reinforcing the idea that formula is good. *See also* G. Hastings, *et al*, *Selling Second Best: How Infant Formula Marketing Works*, GLOBALIZATION AND HEALTH (2020) 16:77.

53. Another advertisement titled "The Judgment Stops Here," is a documentary-styled ad, that purports to encourage mothers to come together and put aside judgment of one another's choices. However, the ad is manipulative, deceptive, and violative of the Code in that it puts breast milk and formula on an even playing field and attempts to chastise any judgment that might be cast in favor or what is clear scientific judgment. In other words, the ad attempts to insulate the formula maker from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint, under the guise of reducing judgment for moms who primarily use infant formula.

54. In an Abbott advertisement for another Similac product, the ad says "when you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by

Similac. It's ***modeled after*** breast milk." Abbott uses a scene of a mother bottle-feeding her baby with a window that opens to a field and in small, light-colored lettering, writes, "No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows. Ingredients not genetically engineered." Abbott claims mothers should trust its "thoughtfully crafted" product which comes after "90 years of crafting" infant formula.[3]

55. Moreover, Abbott has also attempted to market its products specifically to preterm infants, who are in fact at highest risk from the dangers of the product. In 1978, Abbott began marketing "Similac 24 LBW" specifically for premature infants, claiming that the product was introduced to meet the special needs of premature infants. In 1980, Abbott began marketing "Similac Special Care" claiming it was the first low birth weight, premature infant formula with a composition designed to meet fetal accretion rates." In 1988, Abbott introduced and marketed Similac Special Care with Iron, claiming it was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US. Abbott has marketed and sold multiple products specifically targeting "Premature/Low Birth-Weight Infants:" Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30.

56. Defendants have specifically targeted parents of preterm infants in their marketing. Upon information and belief, for example, Defendants have previously run paid Google ads to gain visibility in searches relevant to consumers, and most likely parents, searching for premature baby formulas. To date, Abbott maintains web-based advertisement advising parents that "Since your premature baby didn't get her full 9 months of growth in the womb, her gains in weight, length, and head size will have to be faster than a term-born baby's

[3] (https://www.youtube.com/watch?v=kRaHiTMyYXs).

to reach the size of a full-term baby. This is called 'catch-up growth.' Similac NeoSure is a nutrient-enriched, preterm, post-discharge formula that's clinically shown to support catch-up growth, *on the outside and on the inside.*" (Emphasis in original). Defendant further claim in advertising that Similac NeoSure is the "#1 infant formula brand for premature babies" and the "#1 brand fed in the NICU." Upon information and belief, Defendants previously maintained advertisements which claimed NeoSure was "pediatrician recommended" and the "#1 brand fed in Hospitals" and incredulously, that it is "backed by science" and "nutrition you can trust." The advertisements made no reference to specialized need preterm infants have for human breast milk, and made no mention of the risk of developing NEC or other health problems.

57. On its website, Defendant Abbott also has an "Infant Formula Finder" which mothers can use to help choose "the Best Feeding Option for Your Child." One of the key questions it asks is whether the child was born prematurely. By clicking "yes", the website directs the mother to another page about Similac NeoSure, another Cow's Milk Product. Abbott claims that Similac NeoSure "promotes excellent catch-up growth compared to term infant formula." Abbott includes purported reviews from mothers with preterm infants who discuss how wonderful and safe the products were for their babies. However, there is no mention of the risk of NEC and misleadingly suggests to these vulnerable mothers that the Cow's Milk Products are safe to use for their infants.

58. Recognizing a shift in the medical community towards an exclusive human-based diet for preterm infants, Defendants began heavily promoting "human milk fortifiers," which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk Products.

59. Defendants have designed systematic, powerful, and misleading marketing

campaigns to deceive mothers to believe that: (1) Cow's Milk formula and fortifiers are safe; (2) Cow's Milk Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk Products a first choice. Similarly, Defendants market their products for preterm infants as necessary for growth and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk Products and failing to warn of the deadly disease of NEC and risk of death.

60. Defendants have also engaged in other tactics reminiscent of the tobacco companies by "maneuvering to hijack the political and legislative process, exaggerating economic importance of the industry, manipulating public opinion to gain appearance and respectability, fabricating support through front groups, discrediting proven science, and intimidating governments with litigation" all over the United States and across the world. Sabrina Ionata Granheim, *et al*, *Interference in Public Health Policy: Examples of How the Baby Food Industry Uses Tobacco Industry Tactics*, WORLD NUTRITION, 8(2): 290-298 (2017). To this end, Defendants also attempt to unduly influence and/or manipulate hospitals and medical professionals by donating large amounts of money to coffers disguised as charity for supposed research and advances in science. All the while, their Cow's Milk Products pose the greatest health survival risks to these vulnerable babies. Thus, despite the existence of alternative and safe human milk-based fortifiers, Defendants continue to market and/or sell the Cow's Milk Products under the guise of being a safe product for newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants, like S.A.

The Inadequate Warnings

61. Defendants promote the use of their preterm infant Cow's Milk Products to parents, physicians, hospitals, and medical providers as safe products that are specifically

needed by preterm infants for adequate growth.

62. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk Products, including the significant risk of NEC and death, Defendants did not warn parents or medical providers of the risk of NEC, nor did Defendants provide any instructions or guidance on how to properly use its Cow's Milk Products so as to lower the risk or avoid NEC or death.

63. Defendants did not provide any warning in its labeling, websites or marketing that discusses the risk of NEC (and resulting medical conditions, complications, and injuries) and death with use of their Cow's Milk Products with preterm infants.

Plaintiff S.A. and the Dangerous, Defective Products

64. Plaintiff S.A. was born prematurely at Mercy Health St. Vincent Medical Center, in Toledo, Ohio, on 6/26/2020.

65. Plaintiff S.A. was fed Defendant's Cow's Milk Products, including, but not limited to, Similac Special Care 20 and Similac Special Care 24, starting shortly after her birth.

66. Shortly after being fed Defendants' Cow's Milk Products, Plaintiff S.A. developed NEC.

67. Due to the NEC, which was directly and proximately caused by Defendants' Cow Milk Products, Plaintiff S.A. has suffered and continues to suffer from severe complications and injuries, was forced to undergo multiple surgeries, and continues to suffer severe negative long-term health effects.

68. As a result of Plaintiff S.A.'s NEC and resulting injuries, Plaintiff Austin has suffered financial and economic loss and emotional harm and distress.

69. Plaintiff Austin was not informed that Defendants' Cow's Milk Products carried

the risk of NEC (and resulting medical conditions and/or death).

70. If Plaintiff had been informed that Defendants' Cow's Milk Products were associated with health risks, including NEC, she would not have allowed her child to be fed Defendants' Cow's Milk Products.

COUNT I: STRICT LIABLITY – DESIGN DEFECT

71. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

72. At all times material to this action, Defendants were engaged in the sale of Cow's Milk Products, and sold their Cow's Milk Products, including Defendants' Cow's Milk Products that were fed to and ingested by Plaintiff S.A., in the course of their business.

73. Defendants' Cow's Milk Products fed to and ingested by Plaintiff S.A. were used in a manner reasonably anticipated by Defendants.

74. Defendants' Cow's Milk Products were in a defective condition and unreasonably dangerous when put to the reasonably anticipated use by consumers, including Plaintiff Austin and Plaintiff S.A.

75. Plaintiff Austin and Plaintiff S.A. were damaged as a direct result of the defective condition of Defendants' Cow's Milk Products, which existed when the Products were sold.

76. Defendants, as the manufacturer, seller, and/or distributor of Cow's Milk Products, owed a duty to the consuming public in general, and Plaintiff Austin and her infant child, Plaintiff S.A., in particular, to design, manufacture, distribute, and sell their respective Cow's Milk Products in a manner that was not unreasonably dangerous and are liable despite any care exercised to design a safe product.

77. Defendants' Cow's Milk Products designed, manufactured, distributed and/or

sold by Defendants were in a defective and unreasonably dangerous condition at the time the Products were placed in the stream of commerce for nutritional use for preterm infants.

78. Defendants specifically created, designed, manufactured, distributed and/or sold their Cow's Milk Products for use as nutrition and nutritional supplements for preterm infants, like Plaintiff S.A.

79. Defendants' respective Cow's Milk Products were expected to and did reach the user without substantial change affecting their defective and/or unreasonably dangerous condition.

80. Prior to 2008, Defendants were aware or should have been aware that their respective Cow's Milk Products were not safe for use as nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these Products in such situations.

81. Defendants knew or should have known that the use of their respective Cow's Milk Products with preterm infants was unreasonably dangerous in that its Cow's Milk Products significantly increased the risk of NEC and death.

82. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk Products of the Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits for preterm infants like S.A.

83. Despite the foregoing, Defendants continued to market and sell its defective and/or unreasonably dangerous products to preterm infants.

84. The products were defectively designed and/or unreasonably dangerous, including, but not limited to, the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC

and death;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Plaintiff S.A., to risks of serious bodily injury and death;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so

f. clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;

g. Defendants failed to adopt an adequate or sufficient quality control program; and/or

h. Defendants failed to inspect or test their products with sufficient care.

85. As a direct and proximate cause of the Cow's Milk Products' defective design, which rendered the Products unreasonable dangerous, Plaintiff S.A. has suffered and will continue to suffer severe bodily injury, pain and suffering, disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

86. As a direct and proximate cause of the Cow's Milk Products' defective design, which rendered the Products unreasonable dangerous, Plaintiff Austin has suffered and will continue to suffer emotional harm and distress and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT II: NEGLIGENCE

87. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

88. Defendants, as the manufacturer and/or seller of Cow's Milk Products, owed a duty to the consuming public in general, and to Plaintiff Austin and her infant child, Plaintiff S.A., in particular, to exercise reasonable care in designing, testing, manufacturing, inspecting, labeling, marketing, promoting, distributing, selling, and warning regarding their Cow's Milk Products free of unreasonable risk of harm to users and patients, including Plaintiff and Plaintiff S.A, when said product is used in its intended manner.

89. Defendants, as the manufacturer and/or seller of Cow's Milk Products, had a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

90. Defendants negligently and defectively designed, tested, manufactured, inspected, labeled, marketed, promoted, distributed, sold, and warned regarding the subject Cow's Milk Products.

91. Defendants breached the duty owed to Plaintiff Austin and Plaintiff S.A and acted negligently in their actions, including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data, study, and test to determine if its products were safe for preterm infants;

d. Failing to collect data, study, and test to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions and warn of all known risks and complications associated with the cow-based products;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing NEC and death;

h. Failing to stop or deter its products from being fed to extremely preterm infants like Plaintiff S.A.;

i. Failing to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;

j. Failing to continuously and vigorously study their cow-based products in order to avoid NEC and death in premature infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

l. Failing to adopt an adequate or sufficient quality control program;

m. Failing to warn consumers, including Plaintiff, healthcare providers, the FDA, and the general public of all known risks and complications associated with their cow-based products;

n. Marketing and promoting their cow-based products in a misleading, inadequate, and deceptive manner;

o. Failing to provide periodic or yearly safety reports and risk-benefit analyses;

p. Failing to develop and provide a protocol and/or guidelines to hospitals, physicians, and parents regarding the proper and safe use of the products;

q. Failing to perform the necessary scientific process of collection, detection, assessment, monitoring, and prevention of these adverse effects of feeding its cow-based products; and/or

r. Failing to inspect or test their products with sufficient care.

92. Defendants knew or should have known that their Cow's Milk Products were to be used as nutrition and nutritional supplements with preterm infants, like Plaintiff S.A.

93. Defendants knew or should have known that the use of their Cow's Milk

Products with preterm infants was unreasonably dangerous in that their Cow's Milk Products significantly increased the risk of NEC and death.

94. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk Products of the Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits for premature infants like Plaintiff S.A.

95. Had Defendants not committed negligence, as set forth herein, Plaintiff S.A. would not have been exposed to Defendants' unreasonably dangerous Cow's Milk Products and would not have developed NEC and resulting medical conditions and injuries.

96. As a direct and proximate cause of Defendants' negligence, describe herein, Plaintiff S.A. has suffered and will continue to suffer severe bodily injury, pain and suffering, disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

97. As a direct and proximate cause of Defendants' negligence, described herein, Plaintiff Austin has suffered and will continue to suffer emotional harm and distress and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

98. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

99. At all times material to this action, Defendants were engaged in the sale and

distribution of Cow's Milk Products, including Cow's Milk Products fed to and ingested by Plaintiff S.A., in the course of their business.

100. Defendants' Cow's Milk Products were unreasonably dangerous at the time of sale.

101. Defendants' Cow's Milk Products were unreasonably dangerous when put to the reasonably anticipated use by consumers, including Plaintiff Austin and Plaintiff S.A., who were without knowledge of its unreasonably dangerous characteristics.

102. Defendants' Cow's Milk Products fed to and ingested by Plaintiff S.A., were used in a manner that was reasonably anticipated by Defendants.

103. Defendants failed to adequately warn consumers, including Plaintiff, healthcare providers, the FDA, and the general public of all known risks and complications associated with their Cow's Milk Products, including NEC and resulting medical conditions, complications, and injuries.

104. Plaintiff Austin and Plaintiff S.A. were damaged as a direct result of Defendants' Cow's Milk Products being sold and distributed without an adequate warning.

105. Defendants, as the manufacturers, sellers, and/or distributors of Cow's Milk Products, owed a duty to the consuming public in general, and Plaintiff Austin and her infant child Plaintiff S.A., in particular, as well as healthcare providers, to properly warn and provide adequate warnings and instructions about the dangers, risks, and complications associated with the use of Cow's Milk Products with preterm infants, specifically including but not limited to the risk of NEC and death.

106. Defendants, as the manufacturers, sellers, and/or distributors of Cow's Milk Products, were unreasonable in relying upon any intermediary, including physicians and/or other healthcare providers and/or healthcare staff, to fully warn the end user, including Plaintiff

Austin, of the hidden risks and dangers associated with its Cow's Milk Products, as the magnitude of the risk involved is using Defendants' Cow's Milk Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

107. Defendants, as the manufacturers, sellers, and/or distributors of Cow's Milk Products, failed to fully warn and instruct any intermediary, including physicians, other health care providers, and/or health care staff, of the significant risks and dangers in their Cow's Milk Products.

108. Defendants failed to provide warnings and instructions on its Cow's Milk Products marketed, sold, and/or distributed for use with preterm infants that adequately communicated information on the risks, dangers and safe use of the product to healthcare providers and staff using these products in a Newborn Intensive Care Unit ("NICU"), taking into account the characteristics of, and the ordinary knowledge common to, such prescribing healthcare providers and administering healthcare staff and to specifically warn of the risks and dangers associated with the use of Cow's Milk Products with preterm infants, specifically including, but not limited to, the risk of NEC and death.

109. Rather than provide adequate warnings, Defendants developed relationships which included incentives and financial gain to healthcare providers and facilities for using their Cow's Milk Products within the NICU, such that healthcare providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

110. In addition and/or in the alternative, if healthcare providers and healthcare staff had been properly instructed and warned of the risks associated with the use of Cow's Milk Products with preterm infants, they would have not used such a dangerous product.

111. Defendants, as the manufacturers, sellers, and/or distributors of Cow's Milk

Products, had a duty to hold the knowledge and skill of an expert and were obliged to keep abreast of any scientific discoveries and were presumed to know the result of all such advances.

112. Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in "The Science and Scope of the Problem" Section, knew of the significant risk of NEC with preterm infants and death.

113. Defendants, through their knowledge, review, and survey of the scientific literature, as detailed in "The Science and Scope of the Problem" Section, knew that the use of Cow's Milk Products with preterm infants could cause severe injury, including but not limited to NEC and death.

114. Defendants failed to provide proper warnings and/or instructions regarding their Cow's Milk Products, including but not limited to as follows:

a. Provided no warnings regarding the risk of NEC and death;

b. Provided inadequate labeling that failed to warn of the risks of use of Cow's Milk Products with preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions, guidelines, studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC and/or death;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of Defendants' Cow's Milk Products;

e. Failed to provide instructions to consumers and healthcare providers that Defendants' products carried a significant risk that their Cow's Milk Products could cause babies to develop NEC and die;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk Products significantly increasing the risk of NEC and death and fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that the Cow's Milk Products are known to significantly increase the risk of NEC and death when compared to human milk in preterm infants;

h. Failed to provide well-researched and well-established studies that linked the Cow's Milk Products to NEC and death in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of its products;

j. Failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk Products;

k. Failed to send out "Dear Doctor" letters warning of the risks of NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

l. Failed to advise physicians and healthcare providers that Cow's Milk Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

m. Failed to contain sufficient instructions and warnings on the Cow's Milk Products such that healthcare providers and healthcare staff were not properly warned of the dangers of NEC with use of Cow's Milk Products and preterm infants.

115. If Defendants had fully warned and instructed the intermediary(ies), including physicians, other health care providers, and/or health care staff who provided care and treatment to and/or fed Defendants' Cow's Milk Products to Plaintiff S.A., of the significant risks and dangers in the Cow's Milk Products, including NEC, the intermediary(ies) would not have fed Defendants' Cow's Milk Products to Plaintiff S.A.

116. If Defendants had fully warned and instructed Plaintiff Austin of the significant

risks and dangers in the Cow's Milk Products, including NEC, Plaintiff would not have fed, and/or allowed others to feed, Defendants' Cow's Milk Products to her infant child, Plaintiff S.A.

117. As a direct and proximate cause of Defendant's failure to warn, which rendered the Products unreasonable dangerous, Plaintiff S.A. has suffered and will continue to suffer severe bodily injury, pain and suffering, disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

118. As a direct and proximate cause of Defendants' failure to warn, which rendered the Products unreasonable dangerous, Plaintiff Austin has suffered and will continue to suffer emotional harm and distress and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT IV – NEGLIGENT MISREPRESENTATION

119. Plaintiff realleges all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

120. Defendants provided misleading and false information and/or omitted information in labeling, marketing, distributing, selling, and warning regarding their Cow's Milk Products.

121. Defendants, as the designer, manufacturer, seller, and distributor of their Cow's Milk Products, had a duty to the general public and to Plaintiff Austin to provide truthful, accurate, and complete information about the risks and benefits of using their Products.

122. Defendants failed to exercise reasonable care by failing to provide truthful, accurate, and complete information about the risks and benefits of using their Cow's Milk Products.

123. Because of Defendants' failure to exercise reasonable care, the information provided to consumers, including Plaintiff, regarding their Cow's Milk Products was misleading and/or false, including, but not limited to, the following:

a. Defendant misrepresented that their respective Cow's Milk Products were safe and beneficial for premature infants when they knew or should have known that the Products were unreasonably dangerous and caused NEC, devastating injuries and/or death in premature infants;

b. Defendants misrepresented to parents, physicians, and healthcare providers that their Cow's Milk Products were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth;

c. Defendants misrepresented that their Cow's Milk Products have no serious side effects, when they knew or should have known the contrary to be true;

d. Defendants negligently misrepresented that their Cow's Milk Products are similar or equivalent to human milk;

e. Defendant negligently misrepresented that their Cow's Milk Products were based on current up-to-date science, which made it safe for premature infants;

f. Defendants negligently omitted the material fact that their Cow's Milk Products significantly increase the risk of NEC in premature infants; and

g. Defendants' negligently misrepresented that their Cow's Milk Products contain fats that are good for the baby's brain and similar to breast milk.

124. Plaintiff, who justifiably relied on the information, suffered pecuniary loss as a result.

125. As a direct and proximate cause of Defendants' negligent misrepresentations, described herein, Plaintiff S.A. has suffered and will continue to suffer severe bodily injury, pain

and suffering, disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

126. As a direct and proximate cause of Defendants' negligent misrepresentations, described herein, Plaintiff Austin has suffered and will continue to suffer emotional harm and distress and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

COUNT V – BREACH OF WARRANTIES

127. Plaintiffs reallege all paragraphs previous and subsequent to this paragraph as though fully set forth herein.

128. At all times material hereto, Defendants' Cow's Milk Products were widely sold, distributed, marketed, promoted, and advertised by Defendants as products to safe feed premature babies, including Plaintiff Austin.

129. Defendants marketed, promoted, advertised, sold, and distributed their Cow's Milk Products in the State of Ohio and into the stream of commerce knowing that they would enter the State of Ohio and be used therein.

130. When Defendants placed their Cow's Milk Products into the stream of commerce, they knew of the use for which the Products were intended and expressly and impliedly warranted the Products to be of merchantable quality and to be safe and effective and fit for such use.

131. Defendants made numerous representations about the quality, safety, and effectiveness of the Products, which formed warranties, to Plaintiff S.A.'s healthcare providers and to Plaintiff Austin.

132. At the time of making the warranties, Defendants knew or should have known that, in fact, said representation and warranties were false, misleading, and untrue in that the Products were not safe and fit for their intended use and, in fact, produced serious injuries to the user, including Plaintiff S.A.

133. Plaintiff S.A.'s healthcare providers and Plaintiff Austin reasonably relied upon the expertise, skill, judgment, and knowledge of Defendants and on the express and/or implied warranties that the Products were of merchantable quality and fit for use.

134. The Products did not conform to Defendant's representations and were not of merchantable quality and not safe or fit for their intended use because the Products were, and are, unreasonably dangerous and unfit for the ordinary and expected purposes for which they were used in that they caused injury to Plaintiff S.A. and others far beyond any acceptable or warned of risk or complication.

135. As a direct and proximate result of Defendant's breach of the express and implied warranties, described herein, Plaintiff S.A. has suffered and will continue to suffer severe bodily injury, pain and suffering, disability, emotional harm and distress, loss of enjoyment of life, and economic damages.

136. As a direct and proximate result of Defendant's breach of the express and implied warranties, described herein, Plaintiffs have suffered and will continue to suffer emotional harm and distress and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and requests all applicable damages, including, but not limited to, compensatory damages, punitive damages, costs of this suit, attorneys' fees, pre- and post-judgment interest as permitted by law, and such further relief as the Court deems equitable and just.

PUNITIVE DAMAGES

137. As set forth herein, Defendants acted with a willful, wanton, and/or malicious culpable mental state and such conduct was and is outrageous.

138. As set forth herein, Defendants showed a complete indifference to and/or conscious disregard for the safety of others, including Plaintiff and Plaintiff S.A.

139. Defendants knew or had reason to know a high degree of probability that their actions, as set forth herein, would result in injury to consumers, such as Plaintiff Austin and her infant child, Plaintiff S.A.

140. As set forth herein, Defendants placed in commerce unreasonably dangerous products with actual knowledge of the product's defects.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff S.A. and health and medical care costs, together with interest and costs as provided by law;

2. restitution and disgorgement of profits;

3. reasonable attorneys' fees;
4. the costs of this suit;
5. all ascertainable economic damages;
6. punitive damages; and
7. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury for all issues so triable.

Dated: January 31, 2023

Respectfully submitted,

/s/ Wesley D. Merillat

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